K121422

510(k) Summary of Safety and Effectiveness:

AUG 1 6 2012

Submitter's Name: Toshiba America Medical Systems, Inc.

Address: PO Box 2068,2441 Michelle Drive Tustin, CA 92781-2068

Contact: Charlemagne Chua, Manager Regulatory Affairs

Telephone No.: (714) 730-5000

Device Proprietary Name: DIAGNOSTIC ULTRASOUND SYSTEM

APLIO 500 MODEL TUS-A500 Version 2.1 APLIO 400 MODEL TUS-A400 Version 2.1 APLIO 300 MODEL TUS-A300 Version 2.1

Common Name: Diagnostic Ultrasound System

Classification:

Regulatory Class: II
Review Category: Tier II

Ultrasonic Pulsed Doppler Imaging System - Product Code: 90-IYN

[Fed.Reg.No.:892.1550]

Ultrasonic Pulsed Echo Imaging System - Product Code: 90-IYO

[Fed.Reg.No.:892.1560]

Diagnostic Ultrasonic Transducer – Product Code: 90-ITX

[Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:

Toshiba America Medical Systems believes that this device is substantially equivalent to:

1) Toshiba DIAGNOSTIC ULTRASOUND SYSTEM APLIO 500 MODEL TUS-A500 / APLIO 400 MODEL TUS-A400 / APLIO 300 MODEL TUS-A300 V2.0; 510(k) control number K110870

Device Description:

The DIAGNOSTIC ULTRASOUND SYSTEM APLIO 500 MODEL TUS-A500, APLIO 400 MODEL TUS-A400 and APLIO 300 MODEL TUS-A300 are mobile system. These systems are Track 3 devices that employ a wide array of probes that include flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Indications for Use:

The DIAGNOSTIC ULTRASOUND SYSTEM APLIO 500 MODEL TUS-A500, APLIO 400 MODEL TUS-A400 and APLIO 300 MODEL TUS-A300 is indicated for the visualization of structures, and dynamic processes with the human body using ultrasound and to provide image information for diagnosis in the following clinical applications: fetal, abdominal, intra-operative (abdominal), pediatric, small organs, trans-vaginal, trans-rectal, neonatal cephalic, adult cephalic, cardiac (both adult and pediatric), peripheral vascular, transesophageal, and musculoskeletal (both conventional and superficial).

Declaration of Conformity

This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-1 (applicable portion), IEC 60601-1-2 (applicable portion), IEC 60601-1-4 (applicable portion), IEC60601-2-37 (applicable portions), IEC 62304 (applicable portion) and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

Standards form:

Please see the attached standard form of the IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37 and IEC 62304.



Food and Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993

Toshiba Medical Systems Corporation, Japan % Mr. Charlemagne Chua Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780-2068

AUG 1 6 2012

Re: K121422

Trade/Device Name: Aplio™ 500/400/300 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: July 13, 2012 Received: July 16, 2012

Dear Mr. Chua:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the AplioTM 500/400/300 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

| PST-25BT | <u>PVT-661VT</u> | <u>PVT-770RT</u> | PLT-1204BT |
|-----------|-------------------|-------------------|-------------------|
| PST-30BT | <u>PVT-674BT</u> | <u>PLT-604AT</u> | <u>PLT-1204BX</u> |
| PST-50BT | <u>PVT-675MV</u> | <u>PLT-704AT</u> | <u>PLT-1204MV</u> |
| PST-65AT | <u>PVT-681MV</u> | <u>PLT-704SBT</u> | <u>PET-508MA</u> |
| PVT-375BT | <u>PVT-712BT</u> | <u>PLT-705BTF</u> | <u>PET-510MB</u> |
| PVT-375MV | <u>PVT-745BTF</u> | <u>PVT-705BTH</u> | <u>PET-512MC</u> |
| PVT-382BT | <u>PVT-745BTH</u> | PLT-805AT | <u>PC-20M</u> |
| PVT-382MV | <u>PVT-745BTV</u> | PLT-1202S | <u>PC-50M</u> |

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely Yours,

Janine M. Morris

Acting Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

| | · |
|---|---|
| Indications for Use | |
| 510(k) Number (if known): | |
| Device Name: | Aplio [™] 500 /400/300 Diagnostic Ultrasound System |
| Indications for Use: | |
| 400 MODEL TUS-A400 and AP visualization of structures, and cultrasound and to provide image applications: fetal, abdominal, intrans-vaginal, trans-rectal, neon | ND SYSTEM APLIO 500 MODEL TUS-A500, APLIO PLIO 300 MODEL TUS-A300 is indicated for the dynamic processes with the human body using e information for diagnosis in the following clinical intra-operative (abdominal), pediatric, small organs, natal cephalic, adult cephalic, cardiac (both adult and transesophageal, and musculoskeletal (both |
| Prescription Use <u>X</u> (Part 21 CFR 801 Subpart D) | AND/OR Over-The-Counter Use(21 CFR 807 Subpart C) |
| (PLEASE DO NOT WRITE BELO | W THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) |
| Concurrence of C | DRH, Office of In Vitro Diagnostic Devices (OIVD) |
| (Division Signorfice of <i>In Vitro</i> Diagnostic Dev | ological Devices |
| 510(k) Number 61214 | 22 |

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer:

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | , | , |
|------------------------------------|-----|--------|----------------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | P | P | 2 | P | P | P | | Р | 5,7 |
| Abdominal | P | Р | P | P | P | 2,3 | P | P | P | | Р | 5,7,12 |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | P | P | <u> </u> | | 4,5 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | Р | Р | P | Р | P | 2,3 | Р | P | P | | P | 5,7,12 |
| Small Organ (Note 1) | Р | P | P | | P | 2 | ·P | P | P | | | 4,5,6,7,11 |
| Neonatal Cephalic | P | Р | P | P | P | 3 | P | P | P | | | |
| Adult Cephalic | P | Р | Р | P | P | 3 | P | P | P | | | |
| Trans-rectal | P | Р | Р | | P | 2 | P | Р | P | | Р | 4,5,7,11 |
| Trans-vaginal | Р | Р | Р | | P | 2 | Р | P | P | | P | 4,5,7 |
| Trans-urethral | T | | | | | | | Ī | | | | |
| Trans-esoph. (non-Card.) | | | T | Ĭ | | | | | [| | | |
| Musculo-skeletal (Conventional) | Р | Р | P | | Р | 2 | P | P | Р | | | 4,5,6,7,11 |
| Musculo-skeletal (Superficial) | P | Р | P | | Р | 2 | P | P | Р | | | 4,5,6,7,11 |
| Intravascular | T | Γ | T | T | | | | | | | | |
| Other (Specify) | | Π | Ī | | | | | | | | | |
| Cardiac Adult | P | Р | P | P | P | 3 | P | P | P | P | | 4 |
| Cardiac Pediatric | P | P | P | Р | Р | 3 | Р | P | P | P | | 4 |
| Intravascular (Cardiac) | T | | | Π | | | | Ţ | | | | |
| Trans-esoph. (Cardiac) | Р | Р | P | Р | P | 3 | P | | | | | 4 |
| Intra-cardiac | | Π | T | | | | | | | | | |
| Other (Specify) | T | Π | T | | | | | | | | | |
| Peripheral vessel | Р | Р | P | P | P | 2 | P | P | Р. | | | 4,5,6,7,11 |
| Other (Specify) | T | T | T | | | | T | | | | | |

N = new indication; $P = \overline{prev}$ iously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

Transducer: PST-25BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|---------------------------------|-----|----------|---------|-----|------------------|-----------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | P | P | 3 - | P | P | P | | | 11 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | Р | Р | P | P | P | 3 | Р | P | P | | | |
| Small Organ (Specify) (1) | | | | | | | | | , | | | |
| Neonatal Cephalic | P | P | P | P | P | 3 | Р | P | P | | | |
| Adult Cephalic | P | P | Р | P | Р | 3 | Р | P | P | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | Ī | | | | | | | | | |
| Trans-urethral | Π | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | P | P | P | Р | P | 3 | Р | P | P | P | | 4,13 |
| Cardiac Pediatric | Р | P | Р | P | P | 3 | Р | P | Р | P | | 4,13 |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | Π | T | | | | | | | | | |
| Other (Specify) | | <u> </u> | | | | | | 1 | | | | |
| Peripheral vessel | Γ | | T | | | | | | | | | |
| Other (Specify) | T | T | T | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

A-2

510(k): APLIO 500/400/300, v2.1 Page 190 of 3006

Transducer: PST-30BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | | Operati | | | | | | | | , | |
|---------------------------------|-----|---|---------|-----|------------------|----------------------------|----------|-----------------|----------------------------------|-----------|----------|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | 1 | | | | | | | | | |
| Fetal | | | | | | | | | parimentum Abrushiki babibalikan | | | |
| Abdominal | P | P | P | P | P | 3 | P | P | P | <u> </u> | | 11 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | P | Р | 3 | P | P | P | | <u> </u> | |
| Small Organ (Specify) (1) | | | | | | | | | | <u> </u> | | |
| Neonatal Cephalic | P | P | P | P | P | 3 | P | P | P | | | |
| Adult Cephalic | P | P | Р | P | P | 3 | P | P | Р | | | |
| Trans-rectal | | | | | | | | | | | <u> </u> | |
| Trans-vaginal | | | Ī | | | | | | | | | <u> </u> |
| Trans-urethral | | | | | | | <u> </u> | | | <u></u> | <u> </u> | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | <u> </u> |
| Musculo-skeletal (Conventional) | | | | | | | | | · | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiae Adult | P | P | P | Р | P | 3 | Р | Р | Р | P | | 4,13 |
| Cardiac Pediatric | P | P | P | P | Р | 3 | P | P | P | P | <u> </u> | 4,13 |
| Intravascular (Cardiac) | Ι | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | <u> </u> | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | <u> </u> | | <u> </u> | <u> </u> | |
| Other (Specify) | Т | | T | T | | | | | | 1 | 1 | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Radiological Devices

A-3

510(k): APLIO 500/400/300, v2.1 Page 191 of 3006

Transducer: PST-50BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Эрегаtі | on | | | | | | | | |
|---------------------------------|-----|--------|---------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----------|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | Е | Е | E | Е | Е | 3 | E | E | Е | | | 11 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | Е | E | Е | Е | E | 3 | Е | Е | Е | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | E | Е | E | Е | Е | 3 | E | E | Е | | | <u> </u> |
| Adult Cephalic | Е | Е | Е | E | E | 3 | Е | E | Е | | | |
| Trans-rectal | | | | | | | | 1 | | <u> </u> | <u> </u> | <u></u> |
| Trans-vaginal | | | | | | | | | | <u> </u> | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) |) | | | | | | L | <u> </u> | | | <u> </u> | |
| Musculo-skeletal (Superficial) | | | | Ī | | | | | | | | |
| Intravascular | | | | | | | | | | <u> </u> | | 1 |
| Other (Specify) | | | | | | | | | | <u> </u> | <u> </u> | <u> </u> |
| Cardiac Adult | Е | Е | E | Е | Е | 3 | E | Е | Е | Е | | 4,13 |
| Cardiac Pediatric | Е | Е | ·E | Е | Е | 3 | Е | E | Е | ·E | | 4,13 |
| Intravascular (Cardiac) | | | | | | | | | 1 | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | 1 |
| Intra-cardiac | | | | | | 1 | | | | | <u> </u> | 1 |
| Other (Specify) | | | | | | | | | | | <u> </u> | <u> </u> |
| Peripheral vessel | | | | | 1 | | | 1 | | <u> </u> | | <u> </u> |
| Other (Specify) | | | | | | | | | ŀ | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K090158

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

MAY 2012

A-4

510(k): APLIO 500/400/300, v2.1 Page 192 of 3006

Transducer: PST-65AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Орегаtі | on | | | | | | | | |
|---------------------------------|-----|--------|---------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | Е | Е | E | E | Е | 3 | Е | E | Ē | | | 11 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | · | , | | ŧ | | | | |
| Laparoscopic | | | | | | | | | | | | <u> </u> |
| Pediatric | Е | Е | Е | Е | Е | 3 | Е | Е | Е | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | <u> </u> |
| Neonatal Cephalic | Е | Е | E | Е | E | 3 | Е | Е | Е | | | |
| Adult Cephalic | E | Е | E | Е | E | 3 | Е | E | Е | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | Γ | 1 | | | | | | | | | |
| Trans-urethral | | | T | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | E | Е | E | E | Е | 3 | E | Е | Е | E | | 4,13 |
| Cardiac Pediatric | E | E | Е | E | E | 3 | Е | Е | Е | E | | 4,13 |
| Intravascular (Cardiac) | Τ | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | T | 1 | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | Ι | T | T | | | | | | | | |
| Other (Specify) | Π | T | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K103645

Note I Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Bevices

OIVD

MAY 2012

A-5

510(k): APLIO 500/400/300, v2.1 Page 193 of 3006

Transducer: PVT-375BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|---------------------------------|-----|--------|---------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | Р | Р | P | | Р | 2 | P | P | P | | | 5, 7 |
| Abdominal | P | Р | Р | | P | 2 | P | P | Р | | | 5, 7,11,12 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | | 5, 7,12 |
| Small Organ (Specify) (1) | | | | | | | | - | | <u> </u> | L | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | 1 | | | | | | | | | | | |
| Trans-vaginal | T | | | | | | | | | | | |
| Trans-urethral | | | T | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | T | | | | L | | | | | |
| Cardiac Adult | П | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | T | Π | | Ī | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | T |] | 1 | 1 | | | 1 | | | | | |
| Peripheral vessel | | 1 | | | | | T | | | | | |
| Other (Specify) | | T | | | | | Ţ | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

A-6

510(k): APLIO 500/400/300, v2.1 Page 194 of 3006

Transducer: PVT-375MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operation | on | | | | | | | | |
|------------------------------------|-----|----------|-----------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | A | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | P | P | P | 1 | N | 5,7,8,9,10 |
| Abdominal | Р | Р | P | | P | 2 | P | P | P | | N | 5,7,8,9,10 |
| Intra-operative (Abdominal) | | | | | | | | | | | | <u> </u> |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | Р | P | | Р | 2 | Р | P | P | | N | 5,7,8,9,10 |
| Small Organ (Specify) (1) | | | | | | | | · | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | <u> </u> | | | | | | | | | | |
| Trans-rectal | 1 | | | | | | | | | | | |
| Trans-vaginal | 1 | Π | T | | | | | | | | | |
| Trans-urethral | T | | | | | | | | | - | | |
| Trans-esoph. (non-Card.) | 1 | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | · | | | | | , |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | T | Ī | | | I | | | `` | | | | |
| Cardiac Adult | 1 | | | | | | | | | | T | |
| Cardiac Pediatric | | | | | | | | | | T | | |
| Intravascular (Cardiac) | 1 | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | T | I | T | 1 | 1 | | | | | | |
| Intra-cardiac | T | | T | | | | | | | | | |
| Other (Specify) | Ť | | | | | | | | | | | |
| Peripheral vessel | T | Π | T | | | | | | | | | |
| Other (Specify) | 1 | T | T | | | | T | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Radiological Devices

A-7

AY 2012

Division Of Radiological Devices

510(k): APLIO 500/400/300, v2.1 Page 195 of 3006

Transducer: PVT-382BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operation | on | | | | | | | | |
|---------------------------------|-----|--------|-----------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | Р | Р | P | | Р | 2 | P | Р | P | | | 5, 7 |
| Abdominal | P | Р | P | | P | 2 | P | P | P | | | 5, 7 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | T | | | | | | | | | | , | |
| Pediatric | P | P | P | | P | 2 | P | Р | P | | | 5, 7 |
| Small Organ (Specify) (1) | | | | | | | | | | | | 1 |
| Neonatal Cephalic | Π | Γ | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | T | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | 1 | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | Π | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | T | | | | | | | | | | | |
| Cardiac Adult | | 1. | | | | | | | | | | ĺ |
| Cardiac Pediatric | Π | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | T | T | T | | | | | | | | | |
| Peripheral vessel | T | | | | | | | | | | | |
| Other (Specify) | T | Ī | Ī | | | | | | | | | |

N = new indication, P = previously cleared by FDA, E = added under this appendix

Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

Division of Radiological Devices

A-8

510(k): APLIO 500/400/300, v2.1 Page 196 of 3006

Transducer: PVT-382MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | le of (| Operati | on | | | | | | | | |
|---------------------------------|-----|---------|---------|-----|------------------|----------------------------|----------|-----------------|-------|-----------|-------------|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | Р | Р | P | | P | 2 · | P | P | P | | P | 5, 7,9 |
| Abdominal | Р | P | P | | P | 2 | P | P | P | | P | 5, 7,9 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | P | | Р | 2 | Р | Р | P | | Р | 5, 7,9 |
| Small Organ (Specify) (1) | Г | | 1 | | | | | 1 | | T | | |
| Neonatal Cephalic | | | Ī | | | | | | | | | |
| Adult Cephalic | | | 1 | | | | | | | Ī | *********** | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | 1 | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | ĺ | | | | <u> </u> | | • | 1 | i | |
| Cardiac Adult | | T | | | | | | | | İ | | |
| Cardiac Pediatric | | | 1. | | | | | | | 1 | <u> </u> | |
| Intravascular (Cardiac) | | | | | | | • | | | 1 | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | T | <u> </u> | |
| Intra-cardiac | | | | | | | | | | 1 | | |
| Other (Specify) | | | | | | | <u> </u> | | | | Ì | |
| Peripheral vessel | | | 1 | | | | | İ | | Ť – | | |
| Other (Specify) | 1 | | 1 | | | 1 | İ | | | 1 | | İ |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off) vision of Radiological Devices

A-9 -

510(k): APLIO 500/400/300, v2.1 Page 197 of 3006

Transducer: PVT-661VT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operation | on | | | | | *********** | | | |
|---------------------------------|-----|--------|-----------|-----|------------------|----------------------------|-----|-----------------|-------------|-------------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | 1 | | | | | | | | | İ |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | • | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | Γ | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | J |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | P | P | P | | P | 2 | P | P | P | | | 4,5,7,11 |
| Trans-vaginal | P | P | Р | | P | 2 | P | P | P | | | 4,5,7,11 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | <u> </u> | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | T | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | Ī | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | ľ |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | Ι | | T | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
Division of Radiological Devices

A-10

510(k): APLIO 500/400/300, v2.1 Page 198 of 3006

Transducer: PVT-674BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | le of (| Operati | on | | | | | | | | |
|------------------------------------|-----|---------|---------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | тні | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | ĺ | | |
| Fetal | P | P | P | | Р | 2 | P | P | P | | | 5,7 |
| Abdominal | P | P | P | | P | 2 | Р | P | P | | | 5,7 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | T. | | | | | | | | | | | |
| Pediatric | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | Π | | | i | | | | | | | |
| Adult Cephalic | | 1 | | · | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | 1 | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | T | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | T | | | | | | , | | | |
| Intravascular | | | | | Ī . | | | | | | | |
| Other (Specify) | | | | | | | | | | Ι | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | T | | | | T . | | | | | | |
| Intravascular (Cardiac) | | Π | | | | | | | | | | |
| Trans-esoph. (Cardiac) | T | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | 1 | Τ | T | | | | | | | | | |
| Other (Specify) | | T | T | T | | | Ī | | | 1 | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

| Note 1 | Small orga | n includes | thyroid | breast an | d testicle |
|--------|------------|------------|---------|------------|-------------|
| INUIC | SHIZH OF 2 | m menuaes | uiviOlu | ULCASI AII | 4 16311616. |

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Radiological Devices

A-11

MAY 2012 101400

Toshiba America Medical Systems, Inc.

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PVT-675MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|------------------------------------|-----|--------|---------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | P | P | P | | P | 2 | Р | P | P | | Р | 5,7,8,9,10 |
| Abdominal | Р | P | Р | | P | 2 . | P | P | P | | Р | 5,7,8,9,10 |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | 1 |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | P | P | Р | | P | 2 | Р | P | P | | Р | 5,7,8,9,10 |
| Small Organ (Specify) (1) | | | | | | | | | | | · | |
| Neonatal Cephalic | | | | | | | | | | | | - |
| Adult Cephalic | T | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | T | | Ī | | | | | | | | | |
| Trans-urethral | | | | | | | | | | Ī | | |
| Trans-esoph, (non-Card.) | | | | | | | | 1 | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | 1 | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | Π | T | | | | | | | | | |
| Cardiac Pediatric | | | | | · | | | 1 | | | | |
| Intravascular (Cardiac) | T | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | T | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | M-removed to |
| Other (Specify) | T | Π | | | | | | | | | | |
| Peripheral vessel | T | |] | Τ | | | | | | | | |
| Other (Specify) | T | | 1 | Ţ | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

| Note 1 Small organ includes thyroid, breast and testicle | Note | 1 | Small | organ | includes | thyroid | , breast | and | testicle |
|--|------|---|-------|-------|----------|---------|----------|-----|----------|
|--|------|---|-------|-------|----------|---------|----------|-----|----------|

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801. 109)

(Division Sign-Off)
Division of Radiological Devices

A-12

510kg 2012 5 121477

510(k): APLIO 500/400/300, v2.1 Page 200 of 3006

Transducer: PVT-681MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|------------------------------------|-----|--------|--|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | тні | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | <u> </u> |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric · | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | P | P | P | | P | 2 | Р | P | P | | P | 4,5,7,9,11 |
| Trans-vaginal | P | P | P | | P | 2 | Р | P | P | | P | 4,5,7,9,11 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | The state of the s | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | 1 | | | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

Division of Radiological Devices

A-13

510(k): APLIO 500/400/300, v2.1 Page 201 of 3006 System: Aplio 300, Aplio 400, Aplio 500 v2.1
Transducer: PVT-712BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|------------------------------------|-----|--------|---------|-----|------------------|-----------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | Р | P | | Р | 2 | P | P | P | | P | 5,7 |
| Intra-operative (Abdominal) | | | | | | | | | | <u> </u> | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | <u> </u> | | |
| Pediatric | P | P | P | | P | 2 | P | P | . P | | | 5,7 |
| Small Organ (Specify) (1) | | | | | | | | | | | | <u> </u> |
| Neonatal Cephalic | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Adult Cephalic | | | | | | | | I | | | | |
| Trans-rectal | T | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | T | | T | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | - | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | T | Γ | | | | | | | | [| | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | 1 | | | | | | | <u> </u> |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | 1 | |
| Other (Specify) | | | | | | | | | 1 | | | 1 |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

| Note 1 | Small | organ | includes | thyroid | breast | and | testicle |
|--------|-------|-------|----------|---------|--------|-----|----------|
| | | | | | | | |

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CBE801:109)

(Division Sign-Off)

Division of Radiological Devices

A-14

510k_ MAY 2012 System: Aplio 300, Aplio 400, Aplio 500 v2.1
Transducer: PVT-745BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of | Эрегаці | on | | | | | | | | |
|------------------------------------|--|------|---------|-----|------------------------|-----------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | 1 | | | | | | | | | |
| Fetal | | | | | | | | | | | | <u></u> |
| Abdominal | Е | Е | Е | | E | 2 | Е | Е | E | | | 5,7 |
| Intra-operative (Abdominal) | E | Е | Е | | E | 2 | E | Ē | E | | | 5,7 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | Е | Е | E | | Е | 2 | Е | Е | Е | | | 5,7 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | T | | | | | | | | | |
| Trans-rectal | \top | | | | | | · | | | | | |
| Trans-vaginal | | | T | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | با بجوريها المالية الم | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | T | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | T | | Ī | | | | | | | | | |
| Cardiac Adult | | | 1 | | | | | | | | | T |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | T | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | `` | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | T | Π | | T | | | | | | T | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: None

| Vote | 1 | Small | organ | includes | th | vroid, | breast | and | testicle. |
|------|---|-------|-------|----------|----|--------|--------|-----|-----------|
|------|---|-------|-------|----------|----|--------|--------|-----|-----------|

Prescription Use Only (Per 21 CRT)80 1109)7
(Division Sign-Off)
Division of Radiological Devices

A-15

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Transducer: PVT-745BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | , | | | | |
|------------------------------------|-----|--------|---------|----------|------------------|----------------------------|-----|-----------------|----------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | 1 | | 1 | <u> </u> | | İ | | | | | | |
| Fetal | | | | | | | | | | | | <u> </u> |
| Abdominal | Е | Ε | E | | E | 2 | E | Е | E | | | 5,7 |
| Intra-operative (Abdominal) | E | E | Е | | Е | 2 | Е | Е | E | | | 5,7 |
| Intra-operative (Neuro) | 1. | | | | | | | | | | | |
| Laparoscopic | | | | | | | , | | <u>.</u> | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | E | E | E | | E | 2 | Е | Е | Е | | | 5,7 |
| Neonatal Cephalic | | | | | | | | · . | | | | |
| Adult Cephalic | | | | | | | | | | | | ľ |
| Trans-rectal | | | T | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | T | | | | | [| | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | Ī | | | | | | | | | | |
| Other (Specify) | | Ī | | | | | | | | | | |
| Cardiac Adult | | | | | | T | | | | | | |
| Cardiac Pediatric | | Π | | | | | | | | | | |
| Intravascular (Cardiac) | | Π | T | T | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | 1 | | T | | | | | | | | | |
| Other (Specify) | | 1 | T | | | | | | | | | - |
| Peripheral vessel | | | T | | | | | | | | | |
| Other (Specify) | | Τ | T | 1 | | T | | | | Ī | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: None

| Note 1 Small aroun includes the | arraid broast and tacticle |
|---------------------------------|----------------------------|

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

(Division Sign-Off) Division of Radiological Devices

A-16

System: Aplio 300, Aplio 400, Aplio 500 v2.1 Transducer: PVT-745BTV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|------------------------------------|-----|--------|---------|-----|---|-----------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | P | P | P | | P | 2 | Р | Р | P | | | 5,7 |
| Intra-operative (Abdominal) | P | P | P | | P | 2 | P | P | P | | | 5,7 |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | T | | | | | | | | | | | <u> </u> |
| Trans-rectal | 7 | | Τ | | | | | | | | | |
| Trans-vaginal | | | | | İ | | | | | <u> </u> | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | *************************************** | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | | | T | | | | | | | | | L |
| Other (Specify) | | | | | | | | | | | | <u> </u> |
| Cardiac Adult | | | | Ĭ | | | | | | | | |
| Cardiac Pediatric | T | T | T | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | 1. | | | |
| Peripheral vessel | | T | T | | | | | | | | | |
| Other (Specify) | | | | | T | | | | 1 | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

| Note 1 Small organ includes thyroid, breast and testicle. | Note 1 | Small | organ | includes | thyroid. | breast | and | testicle. |
|---|--------|-------|-------|----------|----------|--------|-----|-----------|
|---|--------|-------|-------|----------|----------|--------|-----|-----------|

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

(Division of Radiological Devices

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

A-17

510(k): APLIO 500/400/300, v2.1 Page 205 of 3006

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Toshiba America Medical Systems, Inc.

System: Aplio 300, Aplio 400, Aplio 500 v2.1

Transducer: PVT-770RT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | | Operation | | | | | | | | | , |
|---------------------------------|-----|---|-----------|-----|------------------|----------------------------|---------|-----------------|----------|-----------|----------|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | <u> </u> | | | · | | | <u> </u> |
| Abdominal | | | | | | <u> </u> | | | | <u> </u> | | <u>'</u> |
| Intra-operative (Abdominal) | | | | | | | | | | <u> </u> | | |
| Intra-operative (Neuro) | | | | | | | | | | | | <u> </u> |
| Laparoscopic | | | | | | 1 | <u></u> | | | | | <u> </u> |
| Pediatric | | | | | | | <u></u> | <u> </u> | | <u> </u> | | |
| Small Organ (Specify) (1) | 1 | | | | | | | | | <u> </u> | | <u> </u> |
| Neonatal Cephalic | | | | | | | | | | | | <u></u> |
| Adult Cephalic | | | | | | | | | | <u> </u> | | 1 |
| Trans-rectal | E | E | Е | | E | 2 | E | E | Е | <u> </u> | <u> </u> | 4,5,7,11 |
| Trans-vaginal | Е | Е | E | | Е | 2 | Ε | E | E | <u> </u> | | 4,5,7,11 |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | T | | | | | | | | | | <u> </u> |
| Musculo-skeletal (Conventional) | | | | | | | | | | | <u> </u> | ļ |
| Musculo-skeletal (Superficial) | | | | | | | | | | <u> </u> | | <u> </u> |
| Intravascular | | | | | | | | <u> </u> | <u></u> | <u> </u> | <u> </u> | <u></u> |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | T | | | | | | | | | | <u> </u> | <u> </u> |
| Cardiac Pediatric | | Τ | | | | | | | <u> </u> | <u> </u> | | |
| Intravascular (Cardiac) | 1 | | | | | | | 1 | | | | 1 |
| Trans-esoph. (Cardiae) | T | | | | | | | | | | | <u> </u> |
| Intra-cardiac | | T | | | | | | | | | | |
| Other (Specify) | T | T | | | | | | | | | <u> </u> | <u> </u> |
| Peripheral vessel | | Ι | | | | | | | | | | <u> </u> |
| Other (Specify) | T | T | | | | | | | | | <u> </u> | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K103645

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)
rision of Radiological Devices

A-18

MAY 2012

System: Aplio 300, Aplio 400, Aplio 500 v2.1 Transducer: PLT-604AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operation | on | | | | | | | y., | · |
|------------------------------------|-----|--------|-----------|-----|------------------|----------------------------|----------|-----------------|-------|-----------|-----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | <u> </u> |
| Abdominal | | | | | | | | | | <u> </u> | | <u> </u> |
| Intra-operative (Abdominal) | | | | | | | | | | ļ | | <u> </u> |
| Intra-operative (Neuro) | | | | | | | | | | ļ | | <u> </u> |
| Laparoscopic | | | | | | | | | | <u> </u> | | <u> </u> |
| Pediatric | | | I | L | l | | <u> </u> | | | | | <u> </u> |
| Small Organ (Specify) (1) | E | Е | E | | E | 2 | E | Е | Е | | | 5,7 |
| Neonatal Cephalic | | | | | | | | | | | | <u> </u> |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | 1 | 1 | T | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | 1 | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | 1 | | | | | | | | | |
| Musculo-skeletal (Conventional) | E | E | Е | | Е | 2 | Е | . E | E | | | 5,7 |
| Musculo-skeletal (Superficial) | Е | E | Е | | E | 2 | E | E | Е | | | 5,7 |
| Intravascular | T | | | | | | | | | L | | |
| Other (Specify) | | | | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | T | | | | | | | | | | | |
| Intravascular (Cardiac) | T | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | , | | | | | 1 | | <u> </u> |
| Other (Specify) | | | | | | | | | 1 | l | | 1 |
| Peripheral vessel | Е | E | E | | Е | 2 | Е | Е | Ε | | | 5,7 |
| Other (Specify) | | T | | 1 | | | | | | | 1 | 1 |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K103645

| Note 1 Small organ includes thyroid, breast and tes |
|---|
|---|

Note 13 2D WMT

Division of Radiological Devices

A-19

MAY 2012

510(k): APLIO 500/400/300, v2.1 Page 207 of 3006

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Transducer: PLT-704AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operation | on | | | | | | | | |
|------------------------------------|--------------|--------|-----------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----------|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | 1 | | | | | | | | | |
| Fetal | | | | | | } | | | | | <u> </u> | |
| Abdominal | | |] | | | | Ĺ | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | <u> </u> | | <u> </u> |
| Intra-operative (Neuro) | \mathbb{T} | | | | | | | | | <u> </u> | | <u> </u> |
| Laparoscopic | | | T | | | | | | | | | <u> </u> |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | E | Е | Е | | E | 2 | E | Е | Ė | | | 5,7 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic . | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | 1 | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | · | | | |
| Musculo-skeletal (Conventional) | Е | Е | Е | | E | . 2 | Е | Е | Е | | | 5,7 |
| Musculo-skeletal (Superficial) | Е | Е | E | | E | 2 | Е | E ' | E | | | 5,7 |
| Intravascular | T | | T | | | | | | | | | |
| Other (Specify) | | | | | | | | | | |] | |
| Cardiac Adult | | | | | | | | | | | | 1 |
| Cardiac Pediatric | 1 | T | T | | | | | | | | | |
| Intravascular (Cardiac) | | | T | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | Π | 1 | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | Е | E | Е | | Е | 2 | Е | E | Е | | | 5,7 |
| Other (Specify) | | T | T | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K103645

| Note | ı | Small | organ | includes | thyroid. | breast | and | testicle. |
|------|---|-------|-------|----------|----------|--------|-----|-----------|
| | | | | | | | | |

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Radiological Devices

A-20

510(k): APLIO 500/400/300, v2.1 Page 208 of 3006

Transducer: PLT-704SBT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | | Operati | | | | | | | , | , · · · · · · · | |
|------------------------------------|-----|---|---------|-----|------------------|----------------------------|-------------|-----------------|---|-----------|-----------------|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | *************************************** | | | |
| Fetal | | | | | | | | | | <u> </u> | | <u> </u> |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | <u> </u> | |
| Laparoscopic | | | | | | | | | | <u> </u> | | |
| Pediatric | | | | | | ļ | | | | <u> </u> | <u> </u> | <u> </u> |
| Small Organ (Specify) (1) | P | P | Р | | P | 2 | P | P | P | | | 5,7 |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | • | | | | |
| Trans-rectal | T | | T | | | | | | | <u> </u> | | <u> </u> |
| Trans-vaginal | T | | | | | | | | | | | |
| Trans-urethral | 1 | | | | | | | | | | | <u></u> |
| Trans-esoph. (non-Card.) | T | | Ī | | | | Ī | , | | | | |
| Musculo-skeletal (Conventional) | P | Р | P | | Р | 2 | P | Р | P | | | 5,7 |
| Musculo-skeletal (Superficial) | P | P | Р | | Р | 2 | Р | P | P | | | 5,7 |
| Intravascular | 7 | | | | | | | | | | T | |
| Other (Specify) | | | T | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | 1 | | | | | <u> </u> | |
| Intra-cardiac | | T | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | <u> </u> | | <u> </u> |
| Peripheral vessel | P | P | Р | | P | 2 | P | P | P | | | 5,7 |
| Other (Specify) | | T | | | | · | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

| Note 1 Si | mall organ | includes | thyroid, | breast and | l testicle. |
|-----------|------------|----------|----------|------------|-------------|
|-----------|------------|----------|----------|------------|-------------|

Prescription Use Only (Per 21 CRF80 1-1097

(Division Sign-Off)

Division of Radiological Devices

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510(k): APLIO 500/400/300, v2.1 Page 209 of 3006

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Transducer: PLT-705BTF

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operation | on | | | | *************************************** | | | | · |
|------------------------------------|-----|--------|-----------|-----|------------------|----------------------------|-----|---|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWĐ | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | Е | Е | Е | | Е | 2 | E | Е | E | | | 5,7 |
| Intra-operative (Abdominal) | Е | Е | E | | Е | . 2 | Е | E | E | | | 5,7 |
| Intra-operative (Neuro) | | | | | | | | | | | | <u> </u> |
| Laparoscopic . | 1 | | T | | | | | | | | | |
| Pediatric | | | T | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | 1 | | T | | | | | | | | | Ī |
| Adult Cephalic | 1 | | 1 | | | | | | | | | |
| Trans-rectal | T - | | T | | | | | | | | | |
| Trans-vaginal | 1 | | T | | | | | | | | | |
| Trans-urethral | T | | 1 | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | T | T | 1 | | | | Ī | | | | | |
| Intravascular | 1 | | | | | | | | | | | |
| Other (Specify) | 1 | | 1 | | | | | | | | | |
| Cardiac Adult | | | | | | | | | | T | | |
| Cardiac Pediatric | | | 1 | | | | Ī | | | T | | T |
| Intravascular (Cardiac) | | T | T | | | | | | | | | |
| Trans-esoph. (Cardiac) | 1 | | T | | | | | | | | | |
| Intra-cardiac | | | T | | | | | | | | | |
| Other (Specify) | 1 | | T | T . | | | | | | | | |
| Peripheral vessel | 1 | | T | Ī | | T | T T | | | | | |
| Other (Specify) | | | T | | | |] | | | T | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K103645

| T - 4 - | 1 | C11 | | | ٠h. | una i d | hennet | ~~4 | tacticle |
|---------|---|------|-------|----------|-----|---------|--------|-----|----------|
| Note: | 1 | Sman | organ | includes | ur | yroru, | DICASI | anu | resurre. |

Prescription Use Only (Per 21 CRF801,109)

(Division Sign-Off)

Division of Radiological Devices

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510(k): APLIO 500/400/300, v2.1 Page 210 of 3006

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Transducer: PVT-705BTH

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|------------------------------------|-----|--------|---------|-----|--|----------------------------|------------|--|-------|-----------|----------|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | Ţ | | | | | | | | | |
| Abdominal | E | Е | E | | Е | 2 | E | E | E | | | 5,7 |
| Intra-operative (Abdominal) | E | E | Е | | Е | 2 | E | E | E | | | 5,7 |
| Intra-operative (Neuro) | 1 | T | | | | | | | | | | |
| Laparoscopic | | | | | | | Ĺ <u>.</u> | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | T | | | | | | | | | | | <u> </u> |
| Neonatal Cephalic | | | | | | | | | | | | <u> </u> |
| Adult Cephalic | | | | | | | | | | | | <u></u> |
| Trans-rectal | | | | | | | [| | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | Ι | | | | | | | | | | |
| Musculo-skeletai (Conventional) | | | | | Action was selected as the sel | | | The state of the s | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | T | | | | | | | | | | | |
| Other (Specify) | T | | T | | | | | | | | | <u> </u> |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | T | | | | | | | | | | 1 |
| Intravascular (Cardiac) | | | | | | | | | | | | <u> </u> |
| Trans-esoph. (Cardiac) | | | | | | | | | | 1 | | <u> </u> |
| Intra-cardiac | | | | | 1 | <u> </u> | | | | <u> </u> | | <u> </u> |
| Other (Specify) | | | | | | | | | | | | 1 |
| Peripheral vessel | | | | | | | | | | 1 |] | |
| Other (Specify) | T | 1 | | | | | | 1 | | | <u> </u> | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K103645

| Note | 1 Small organ | -includes | thyroid. | breast an | d testicle. |
|------|---------------|-----------|----------|-----------|-------------|

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Radiological Devices A-23

510(k): APLIO 500/400/300, v2.1 Page 211 of 3006

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

System: Aplio 300, Aplio 400, Aplio 500 v2.1
Transducer: PLT-805AT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|---------------------------------|-----|--------|---------|-----|------------------|-----------------------|-----|-----------------|-------|---|------------|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | L <u>.</u> | <u> </u> |
| Abdominal | | | | | | | | | | | | <u></u> |
| Intra-operative (Abdominal) | | | | | | | | | | <u> </u> | | <u> </u> |
| Intra-operative (Neuro) | | | | | | | | | | <u>l. </u> | | <u> </u> |
| Laparoscopic | | | | | | | | | | | | <u> </u> |
| Pediatric | | | | | | | | | | | | <u> </u> |
| Small Organ (Specify) (1) | P | Р | P | | P | 2 | P | P | Р. | | | 5,6,7,11 |
| Neonatal Cephalic | | | | | | | | | | | | I |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | Ţ | | | | | | | | | - |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | Р | | P | 2 | P | Р | P | | | 5,6,7,11 |
| Musculo-skeletal (Superficial) | Р | P | Р | | P | 2 | Р | P | P | | | 5,6,7,11 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | 1 | | | | | | | |
| Cardiac Adult | | | | | | | Ī | | | | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | |] | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | P | P | P | | P | 2 | P | P | P | | | 5,6,7,11 |
| Other (Specify) | | | | | | | | T | | 1 | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870 -

| Note | 1 Small | Lorgan | includes | thyroid | hreast : | and testicle. |
|------|---------|--------|----------|---------|----------|---------------|

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

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Division of Radiological Devices

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MAY 2012

510(k): APLIO 500/400/300, v2.1 Page 212 of 3006

Transducer: PLT-1202S

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application . | Mod | e of (| Operati | on | | | | | | | | |
|---------------------------------|-----|----------|---------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | T | | | | | | | | | |
| Intra-operative (Abdominal) | P | P | Р | | P | . 2 | P | | P | | | 4,5,11 |
| Intra-operative (Neuro) | Π | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | Р | P | P | | Р | 2 | P | | P | | | 4,5,11 |
| Neonatal Cephalic | 1 | <u> </u> | T | | | | | | | T | | |
| Adult Cephalic | | | 1 | | | | | | | | | |
| Trans-rectal | 1 | | 1 | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | · . |
| Trans-urethral | | | 1 | | | | | | | | | |
| Trans-esoph. (non-Card.) | | <u> </u> | 1 | | | | | T T | | | | T |
| Musculo-skeletal (Conventional) | Р | P | Р | 1 | P | 2 | Р | | P | · | | 4,5,11 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | | P | | | 4,5,11 |
| Intravascular | T | Ī | T | | | | | | | | | |
| Other (Specify) | | Ī | | | | | | | - | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | 1 | 1 | T | | | | T | | T | | |
| Intravascular (Cardiac) | П | T | T | T | | | | | | | | |
| Trans-esoph. (Cardiac) | | | T | T | | | | | | | | |
| Intra-cardiac | | T | T | | | | | | | | | |
| Other (Specify) | T | | T | | | | | | | | | |
| Peripheral vessel | N | N | N | | N | 2 | N | | N | T | | 4,5,11 |
| Other (Specify) | 1 | Τ | 1 | 1 | 1 | T | | 1 | | Ī | 1 | T T |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD
Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

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510(k): APLIO 500/400/300, v2.1 Page 213 of 3006

Transducer: PLT-1204BT

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operation | on | | | | | | | | |
|------------------------------------|-----|--------|-----------|-----|------------------|-----------------------|----------|-----------------|-------|-------------|----------|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) | тні | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | 1 | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | <u> </u> | | | | | |
| Laparoscopic | Ţ | | | | | | | | | | | |
| Pediatric | | | 1 | | | | | 1 | | | | |
| Small Organ (Specify) (1) | P | Р | P | | P | 2 | P | P | P | | | 4,5,6,7,11 |
| Neonatal Cephalic | | | | | · | | | | | | | <u> </u> |
| Adult Cephalic | T | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | <u> </u> | 1 |
| Trans-vaginal | Ţ | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | |] | |
| Trans-esoph. (non-Card.) | | | | | | | | · | | | | <u> </u> |
| Musculo-skeletal (Conventional) | P | Р | Р | | Р | 2 | P | Р | Р | | | 4,5,6,7,1 |
| Musculo-skeletal (Superficial) | P | P | P | | P | 2 | P | P | P | | | 4,5,6,7,1 |
| Intravascular | T | | | | | | | | | | <u>l</u> | <u> </u> |
| Other (Specify) | 7 | T . | 1 | | T . | | | | | | | 1 |
| Cardiac Adult | | | | | | | | | | 1 | | |
| Cardiac Pediatric | | | | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | | | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | Ι | | | | | | | | 1. | | 1 |
| Peripheral vessel | N | N | N | | N | 2 | N | N | N | | | 4,5,6,7,1 |
| Other (Specify) | T | | | | | | | 1 | 1 | 1 | 1 | 1 |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off

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510(k): APLIO 500/400/300, v2.1 Page 214 of 3006

Aplio 500 v2.1 System: Transducer: PLT-1204BX

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|------------------------------------|-----|--------|---------|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | <u></u> |
| Abdominal | | | | | | | | | 4.155 | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | 1 | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | <u> </u> | | |
| Small Organ (Specify) (1) | P | P | P | | P | 2 | Р | P | P | | | 5,7 |
| Neonatal Cephalic | | | | | | | | | | | | <u> </u> |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | - | | | | | | <u> </u> |
| Trans-vaginal | T | | | | | | | | | | | L |
| Trans-urethral | | | | | , | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | P | P | Р | | P | 2 | Р | P | P | | | 5,7 |
| Musculo-skeletal (Superficial) | P | P | Р | | P | 2 | Р | P | P | | | 5,7 |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | T | | | | | | | | | | |
| Cardiac Adult | | Π | | T | | | |] | | | | 1 |
| Cardiac Pediatric | T | | | | | | | | | | | |
| Intravascular (Cardiac) | | T | | | | | | | | | | |
| Trans-esoph. (Cardiac) | | Γ | T | | | | | | | | | |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | T | | 1 | | | | | | | |
| Peripheral vessel | P | P | Р | | Р | 2 | Р | P | P | | | 5,7 |
| Other (Specify) | - | T | T | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

| Note 1 | I | Small | organ | includes | thyroid, | breast | and | testicle. |
|--------|---|-------|-------|----------|----------|--------|-----|-----------|
|--------|---|-------|-------|----------|----------|--------|-----|-----------|

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color) '

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109) (Division Sign-Off) Division of Radiological Devices

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510(k): APLIO 500/400/300, v2.1 Page 215 of 3006

Transducer: PLT-1204MV

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operati | on | | | | | | | | |
|------------------------------------|-----|--------|---------|-----|------------------|----------------------------|-------------|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | тні | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | T | | | | | | | | | | | |
| Laparoscopie | T | | | | | | | | | | | |
| Pediatric | | | T | | | | | | | | | |
| Small Organ (Specify) (1) | Р | Р | P | | P | 2 | P | P | P | | P | 5,7,8,9,10 |
| Neonatal Cephalic | 1 | | | | | | | | | | | |
| Adult Cephalic | 1 | | | | | | | | | | | |
| Trans-rectal | 1 | | 1 | | | | | | | | | |
| Trans-vaginal | 1 | | | | | | | | | | | |
| Trans-urethral | 1 | | 1 | | Ī | | | | | | | |
| Trans-esoph. (non-Card.) | | | 1 | Ì | | | | | | | | |
| Musculo-skeletal (Conventional) | Р | Р | Р | | Р | 2 | P | Р | P | | Р | 5,7,8,9,10 |
| Musculo-skeletal (Superficial) | P | P | P | | P | . 2 | Р | Р | P | | P | 5,7,8,9,10 |
| Intravascular | 1 | | | | | | | | | | | |
| Other (Specify) | T | | T | i | | 1 | | | | | | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | T | | 1 | 1. | | | | | | | | |
| Intravascular (Cardiac) | T | | 1 | | 1 | 1 | | | | | | |
| Trans-esoph. (Cardiac) | T | Ī | Ī | ĺ | | Ī | | | | | | |
| Intra-cardiac | I | | | | | | | | | | | |
| Other (Specify) | T | | T | | | | | | | | | |
| Peripheral vessel | P | P | P | Τ. | Р | 2 | Р | Р | P | Ţ | Р | 5,7,8,9,10 |
| Other (Specify) | Τ. | Γ | | T | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off)

Division of Radiological Devices

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51/Ak 2012 1 1 2 1 4 2 2

Transducer: PET-508MA

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation B M PWD CWD Color Combined TH1 Dynamic Power CH1 4D Other | | | | | | | | | | | |
|------------------------------------|---|---|-----|-----|------------------|-----------------------|----------|-----------------|-------|-----------|----|-----------------|
| Specific . (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | · | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | T | | Ι | | | | | | | | | |
| Adult Cephalic | T | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | T | | T | | | | | | | | | |
| Trans-urethral | T | Γ | T | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | T | | Ī | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | Ī | | | 1 | <u> </u> | | | | | |
| Cardiac Adult | 1 | | | 1 | | 1 | <u> </u> | | | 1 | | |
| Cardiac Pediatric | | | T | | | | <u> </u> | | | | | |
| Intravascular (Cardiac) | 1 | | | | | | | | | 1 | I | |
| Trans-esoph. (Cardiac) | Е | Е | Е | Е | Е | 3 | Е | | | | | 4,13 |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | T | | T | | | | | | | I | | |
| Peripheral vessel | T | Π | T | | | | J T | | | T | | [|
| Other (Specify) | 1 | | 1 | | <u> </u> | | | | | 1 | | I |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: None

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Prescription Use Only (Per 21 CRF801.109)

(Division Sign-Off) ision of Radiological Devices

510(k): APLIO 500/400/300, v2.1 Page 217 of 3006

Transducer: PET-510MB

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operatio | on | | ************************************** | | | | | | |
|------------------------------------|-----|--------|----------|-----|------------------|--|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | M | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | [| | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | T | | | | | | | | | | | |
| Pediatric | | | | | | | | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | | | | | | | | | | | |
| Trans-urethral | | | | | | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | T | | | | | | | | | |
| Intravascular | 1 | | | | | | | | | | | |
| Other (Specify) | | | | | | | | , | | | · | |
| Cardiac Adult | | | | | | | | | | | | |
| Cardiac Pediatric | | | T | | | | | | | | | |
| Intravascular (Cardiac) | | | | | | | | | | | | |
| Trans-esoph. (Cardiac) | P | P | P | Р_ | P | 3 | Р | | | | | 4,13 |
| Intra-cardiac | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | |
| Peripheral vessel | | | | | | | | | | | | |
| Other (Specify) | T | | T | | | | | | | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer; K110870

| Note | 1 | Small | organ | includes | thyroid | breast | and | testicle |
|-------|---|-------|--------|----------|----------|--------|-----|-----------|
| INOLE | L | Siman | UIZAII | miciades | utyroid, | DICASI | anu | testicic. |

Prescription Use Only (Per 21 CRF801.109)

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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

Transducer: PET-512MC

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | e of (| Operation | on | | | | | | | | |
|------------------------------------|-----|----------|-----------|-----|--|----------------------------|----------|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | 1 | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | 1 | | T | | | | | | | | | |
| Pediatric | T | | 1 | | | | | | | | | |
| Small Organ (Specify) (1) | | | 1 | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | 1 | | T | | | | | | | | | |
| Trans-rectal | T | | Ī | | | | | | | | | |
| Trans-vaginal | 1 | | 1 | | | | | | | | | |
| Trans-urethral | 1 | | ĺ | | Ī | | | | | | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | 1 | <u> </u> | 1 | , | | | | | | | | |
| Other (Specify) | | | | | | | | | | | | Ì |
| Cardiac Adult | 1 | | 1 | | | | | | | Ĭ T | | |
| Cardiac Pediatric | 1 | <u> </u> | 1 | | | | | | | 1 | | |
| Intravascular (Cardiac) | | | | | | 1 | <u> </u> | | | | | |
| Trans-esoph. (Cardiac) | Е | Е | Е | Е | Е | 3 | E | | | | | 4,13 |
| Intra-cardiac | T | Π | T | T | ************************************** | | <u> </u> | | | T | | |
| Other (Specify) | 1 | | | | İ | | | T | | T | | T |
| Peripheral vessel | 1 | | 1 | | | | | | | | | |
| Other (Specify) | 1 | 1 | 1 | | T T | 1 | T | | | Ī | | 1 |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K103629

Note 1 Small organ includes thyroid, breast and testicle.

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

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| System: | Aplio 300 | , Aplio | 400, | <u>Aplio</u> | <u>500</u> | v2.1 | |
|---------|-----------|---------|------|--------------|------------|------|--|
| T | DO 30 | | | | | | |

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mode of Operation | | | | | | | | | | | |
|------------------------------------|-------------------|---|--|-----|------------------|----------------------------|-----|-----------------|-------|-----------|----|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | ТНІ | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | | | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | | | | | |
| Laparoscopic | | | | | | | | | | | | |
| Pediatric | T | | | | | | | | | | | |
| Small Organ (Specify) (1) | T | | | | | | | | | | | |
| Neonatal Cephalic | T | | | | | | | | | | | |
| Adult Cephalic | T | | | | | | | | | | | |
| Trans-rectal | | | | | | | | | | | | |
| Trans-vaginal | | Π | | | | | | | | | | 1 |
| Trans-urethral | | | | | | | | | | | | 1 |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | | | | | | | | | | | | |
| Intravascular | 1 | Ī | | | | | | | | T | | Ì |
| Other (Specify) | | Г | | | | 1 | | | | | | ĺ |
| Cardiac Adult | Т | | | Р | | | | | | | | |
| Cardiac Pediatric | 1 | | | P | | | | | | | | |
| Intravascular (Cardiac) | 1 | 1 | Ì | | <u> </u> | | | | | | | İ |
| Trans-esoph. (Cardiac) | T | T | | | | | | | | | | |
| Intra-cardiac | T | Γ | T | 1 | | | | | | | | |
| Other (Specify) | T | | | l | | | | | | | | |
| Peripheral vessel | T | Π | | Р | | | | | | | | |
| Other (Specify) | 1 | | T | | | | | | | T | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

| Mata | 1 Conall as | gan include | a threeoid | beneat and | tactiola |
|------|-------------|-------------|------------|------------|----------|
| | | | | | |

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510(k): APLIO 500/400/300, v2.1 Page 220 of 3006

Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT

| System: | Aplio 300, Aplio 400, Aplio 500 v2.1 | |
|------------|--------------------------------------|--|
| Transducer | PC-50M | |

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

| Clinical Application | Mod | Mode of Operation | | | | | | | | | | |
|------------------------------------|-----|-------------------|----------|-----|---------------------------------------|----------------------------|-------------|-----------------|--|-----------|-------------|-----------------|
| Specific (Tracks 3) | В | М | PWD | CWD | Color Doppler | Combined (Specify) * | THI | Dynamic Flow | Power | CHI 2D | 4D | Other [Note] |
| Ophthalmic | 1 | | | | | | | | | | | |
| Fetal | | | | | | | | | | | | |
| Abdominal | | | | | | | | | | | | |
| Intra-operative (Abdominal) | T- | <u> </u> | | | | | | | | | | |
| Intra-operative (Neuro) | | | | | | | | · | | | | |
| Laparoscopic | | | | | | | | 1 | | | | |
| Pediatric | | | | | | | 1 | | | | | |
| Small Organ (Specify) (1) | | | | | | | | | | | | |
| Neonatal Cephalic | | | | | | | | | | | | |
| Adult Cephalic | İ | | 1 | | | | | | was the contract of the contra | | | |
| Trans-rectal | 1 | | | | | | | | ******** | | | |
| Trans-vaginal | | | † | | | | | | | | | |
| Trans-urethral | | | | | | | | | | ! | | |
| Trans-esoph. (non-Card.) | | | | | | | | | | | | |
| Musculo-skeletal (Conventional) | | | | | | | | | | | | |
| Musculo-skeletal (Superficial) | 1 | | | | | | | | | | | |
| Intravascular | | | | | | | | | | | | |
| Other (Specify) | | | | | | | | | | 1 | | |
| Cardiac Adult | T | | | Р | | | | | | | | |
| Cardiac Pediatric | | | | Р | | | | | | | | |
| Intravascular (Cardiac) | | | | | · · · · · · · · · · · · · · · · · · · | | | | | | | |
| Trans-esoph. (Cardiac) | 1 | **** | | | | | | <u> </u> | | 1 | ********* | ** 1 <u></u> |
| Intra-cardiac | T | | | | | | | | | | | |
| Other (Specify) | | | Ì | | | | | | | | | |
| Peripheral vessel | | | | Р | | | | | | | | |
| Other (Specify) | 1 | | | | | | | | *************************************** | | | |

N = new indication; P = previously cleared by FDA; E = added under this appendix Previous 510(k) of the transducer: K110870

| Note | 1 | Small | organ | includes | thyroid | breact | and | testicle |
|------|---|-------|-------|----------|---------|--------|-----|-----------|
| MULC | L | Sman | urgan | niciudes | шугона, | Dreast | anu | testicie. |

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Note 2 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Note 3 Combined mode includes B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD; 2D/CWD; BDF/CWD

Note 4 TDI

Note 5 ApliPure

Note 6 MicroPure

Note 7 Precision Imaging

Note 8 STIC

Note 9 3D Color (Volume Color)

Note 10 STIC Color

Note 11 Elastography

Note 12 Fusion

Note 13 2D WMT